

Ministry of Health of Czech Republic  
Dr. David Rath  
Minister of Health  
Palackého nám. 4  
128 01 Praha 2  
Czech Republic

Dear Minister,

I am writing to you on behalf of the Pharmaceutical Group of the European Union (PGEU), the European association representing community pharmacists in Europe. PGEU Members are the professional bodies and community pharmacists' associations of 30 European countries.

In the context of the current discussions in the Czech Republic on the measures proposed for the distribution of medicines, I would like to express, on behalf of the PGEU Executive Committee, our concerns on the effects and repercussions that such changes could bring to the health system and the proper functioning of pharmacy services. We are convinced that it is in the best interest of the health system and of Czech patients that the quality and the sustainability of pharmaceutical services are not jeopardised. All over Europe, citizens highly value the role that pharmacists play in society; they trust his/her services, which also register a high level of satisfaction.

Community pharmacists are part of national health systems under the framework of social security reimbursement schemes. Their activities and professional responsibilities have a direct impact on the provision of health care. Member States recognise and value that impact by imposing on the profession clear rules aiming at meeting public health objectives.

We believe it is important that any proposal, which would bring changes to the way pharmaceutical services are provided in Europe, like the ones proposed in your country, should be carefully examined. Member States have on several occasions asked the European Commission to perform an extensive Health Impact Assessment before proposing any measure that could affect existing national health systems. In our analysis, Member States themselves should carry out such types of exercise when proposing measures which would significantly change the way pharmaceutical services are provided in one country.

So far experiences have demonstrated that the separation between the prescribing role of the medical doctor and the dispensing role of the pharmacist is the most effective way to ensure public interest. It also provides an efficient and high quality services in both areas.

When examining competition in liberal professions, the Commission itself recognised the importance in certain sectors of maintaining certain reserved rights to one profession *“where there is the need to protect practitioner’s independence or personal liability”*.<sup>1</sup> Evidence shows that this is the case in the pharmaceutical sector.

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<sup>1</sup> Communication from the Commission: Report on Competition in Professional Services. **COM (2004) 83 final**.

You will surely be aware that the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Standing Committee of European Doctors (CPME) have agreed on a set of guidelines aimed at regulating the relationship between medical doctors and the industry<sup>2</sup>. According to the same reasoning, nearly all Member States have implemented clear legislation to maintain the separation between the dispensing and the prescribing function, with the final objective of protecting public interest and supporting the medical profession to maintain their total independence from other players, who are active in the pharmaceutical sector. This ensures that prescribing is based only on clinical need.

In addition, we would like to point out that EU legislation recognises the pharmacist as a “*specialist in medicinal products*”<sup>3</sup> and stipulates that the pharmacist’s responsibilities include “*the preparation, testing, storage and supply of medicinal products in pharmacies open to the public*” and “*the provision of information and advice on medicinal products*”. Moreover, in relation to the proposed measures directed to encourage the distribution of medicines out of the pharmacies I would like to highlight the importance of the effective professional supervision by the pharmacist and the importance of face-to-face contact between the pharmacist and the patient when dispensing the medicine. They have been recognised as an indispensable element by the European Court of Justice on several occasions, the last one being the DocMorris ruling<sup>4</sup>. In our view, it is important to ensure that the direct professional responsibility of the pharmacist, in relation to the activities carried out in the pharmacy, is not diluted.

EU and national legislation clearly recognise the special nature of medicines; all aspects of the pharmaceutical sector from its authorisation to the market to their disposal are highly regulated. A move aiming at dispensing certain medicines outside pharmacies and without the supervision of a highly qualified professional expert is against the principle of rational and appropriate use of medicines. Furthermore, experience shows that this move is not without consequences to public health.

This can be easily concluded by the analysis of data from those countries that have notification procedures of admissions in hospital emergency services related to the overuse or misuse of medicines.

We should keep in mind that the way you get a medicine is a key element, which contributes to the perception citizens have of medicinal products. As evidence shows, overuse from easily accessible medicines is a common phenomenon that should be appropriately addressed.

As more and more effective and therefore potent medicines are reclassified from prescription-only control to non-prescription status, this will be an even more important consideration.

With full understanding of your high level responsibilities and the authority you represent at national and European level, I would kindly ask you to take into consideration the points raised above and to acknowledge in your deliberations the essential contribution that pharmacy services provide to citizens, a contribution that

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<sup>2</sup> Joint Declaration of CPME and EFPIA on the Cooperation between the medical professional and the pharmaceutical industry. See: [http://www.efpia.org/4\\_pos/EFPIACPMEJointdeclaration.pdf](http://www.efpia.org/4_pos/EFPIACPMEJointdeclaration.pdf) or <http://www.cpme.be>

<sup>3</sup> Directive 2005/36/EC on the recognition of professional qualifications; and Council Directive 85/432/EEC concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of certain activities in the field of pharmacy.

<sup>4</sup> Case C-322/01 - Deutscher Apothekerverband v 0800 DocMorris and Jacques Waterval.

in our analysis will be greatly jeopardised if the proposed measures would be implemented.

PGEU is available to provide all the information and clarifications you might consider relevant and will be very pleased to offer any collaboration you may need on this issue.

Yours sincerely,

(Originally Signed)  
Luís Matias  
PGEU President